



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,774	07/25/2001	Manaud Pierre Frederic De Raspide	PC10915A	5154
28880	7590	05/04/2006	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/912,774	Applicant(s) DE RASPIDE ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5-10, 13, 14, 17-25, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-10, 13, 14, 17-25, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 2/16/2006. Claims 2, 16 and 27-37 are canceled; claims 1, 41 and 42 are amended. Therefore, claims 1, 5-10, 13, 14, 17-25, 41 and 42 are pending.

Drawings

Applicants acknowledge the objection to the drawings and indicate that corrected drawing will be filed upon identification of allowable subject matter. However, the objection will not be held in abeyance and the objection will be made in all office actions until applicants comply with the drawing requirements.

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5-10, 13, 14, 17-25, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. The specification does not provide support for small dispersing eletriptan on

Art Unit: 1618

the seed. The specification at paragraph [0017] of the published application describes layering a solution of the drug onto the pharmaceutically acceptable seed.

Applicants may point to the specification for support of dispersing the eletriptan on seed and amend the claims to indicate that the eletriptan is layered on to the seed or explain why dispersing may be the same as layering.

3. The previous rejection of claims 1, 2, 5, 6-10, 13, 14 and 16-25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims, which removed the first layer from claim 1.

Regarding the rejection of claim 41 as being indefinite because eletriptan is contained in the core, the core being the non-pareil seed coated with the eletriptan. The rejections as it regard to claim 41 are withdrawn.

Regarding claim 42, layering of the eletriptan onto the seed has support in the specification and dispersing does not have support. Applicants may make that amendment.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 5-10, 13, 14, 17-25, 41 and 42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 00/06161) in view of Stevens et al. (US 5,112,621).

Jackson discloses the use of eletriptan for treating migraine recurrence, in a dual-, sustained-, delayed-, controlled-, or pulsed-release dosage form (abstract). Jackson discloses that both the hydrobromide salt and the hemisulfate form of eletriptan are known in the art (page 1, lines 9-13). Jackson specifically discloses that the formulation of their invention can be in a pulsed-release form, including the sigmoidal releasing pellets discussed in US 5,112,621.

Stevens (referred to immediately above) discloses a sustained release pharmaceutical composition, which comprises microparticles comprising an active agent (abstract). Furthermore, said microparticles are coated with a coating mixture comprising ethyl cellulose and an acrylic resin made of a polymer of acrylic and methacrylic ester, wherein the resin contains trimethylammonium methacrylate chloride (abstract). Stevens also discloses that the uncoated microparticles may comprise excipients such as a diluent and a binder. The diluent may be microcrystalline cellulose, and the binder may be hydroxypropylmethyl cellulose (column 1, line 61 - column 2, line 2). Additionally, a plasticizer, such as triethyl citrate, may be included (column 2, line 8). Stevens also discloses that the microparticulates can be in a unit dosage form, such as a hard gelatin capsule (column 1, lines 49-51).

One of ordinary skill in the art would have been motivated to combine the teachings of Jackson and Stevens as this is precisely what is discussed in the Jackson et al. reference. This reference clearly refers to the Stevens reference as a teaching when a formulation with sigmoidal release is desired.

Applicants argue that using the consisting essentially of language in the claim 1 overcomes the Jackson art that uses a mixture of ethyl cellulose and acrylics in the coating.

Response to Arguments

6. Applicants' arguments filed 2/16/06 have been fully considered but they are not persuasive because the claim 1 recites comprising in line 2 of the claim, and the comprising language is open and does not exclude the ethylcellulose.

The claim may be amended to include a provision that the coating composition does not contain ethylcellulose if there is a disclosure for the presence of ethylcellulose in the instant coating composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

